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**Evaluation of the Safety and Tolerability of KA34 in a Phase 1, Double-Blind, Dose Escalation Trial in Patients with Knee Osteoarthritis**

**Grant Award Details**

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Evaluation of the Safety and Tolerability of KA34 in a Phase 1, Double-Blind, Dose Escalation Trial in Patients with Knee Osteoarthritis

**Grant Type:** Clinical Trial Stage Projects

**Grant Number:** CLIN2-10388

**Project Objective:**

Evaluation of the Safety and Tolerability of KA34 in a Phase 1, Double-Blind, Dose Escalation Trial in Patients with Knee Osteoarthritis

**Investigator:**

<b>Name:</b>	Leonardo Sahelijo
<b>Institution:</b>	California Institute for Biomedical Research
<b>Type:</b>	PI

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**Disease Focus:** Osteoarthritis, Bone or Cartilage Disease, Arthritis

**Award Value:** \$8,447,523

**Status:** Active

**Grant Application Details**

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**Application Title:** Evaluation of the Safety and Tolerability of KA34 in a Phase 1, Double-Blind, Dose Escalation Trial in Patients with Knee Osteoarthritis

**Public Abstract:****Therapeutic Candidate or Device**

KA34 is an intra-articularly delivered small molecule therapeutic candidate which directs the differentiation of endogenous stem and progenitor cells

**Indication**

Osteoarthritis

**Therapeutic Mechanism**

KA34 promotes the differentiation of cartilage endogenous stem cells through increased chondrogenic gene expression to generate healthy chondrocytes. KA34 will potentially limit the progression of and / or reverse the osteoarthritis disease process. KA34 may generate new cartilage matrix within the pre-existing matrix without fibrotic cartilage formation and aims to improve the clinical joint scores.

**Unmet Medical Need**

There are no approved disease-modifying therapies available which stop the joint damage in 30 million osteoarthritis patients in the United States. This grant will support execution of a Phase 1 clinical trial to evaluate the safety of the small molecule, KA34, which stimulates cartilage repair.

**Project Objective**

Completion of a Phase I clinical trial for KA34

**Major Proposed Activities**

- Completion of clinical site selection, start-up activities and execution of the Phase I single and multiple ascending dose clinical study with KA34
- Data analysis and reporting on the Phase I single and multiple ascending dose clinical study with KA34 in osteoarthritis patients
- Evaluation of potential KA34 treatment-associated biomarkers to support future clinical development of KA34 in osteoarthritis

**Statement of Benefit to California:**

Almost six million adults in California are affected with arthritis, with osteoarthritis being the most common manifestation of this disease. For the average patient, ~\$129,600 of direct medical costs are incurred in their lifetime and 50% need a total joint replacement, an invasive surgical procedure. KA34 was developed for delivery by a local injection to the affected joint. It aims to limit the progression of OA which may reduce medical costs and burden to the primary care givers.

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